K034020

JAN 2 1 2004

Section 6

510(k) Summary of Safety and Effectiveness Information

4 Fr Single Lumen Groshong®NXT PICC Catheter

6.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5439
Fax Number:	(801) 595-4903
Contact Person:	Peggy Keiffer
Date of Preparation:	12/22/03

6.2 Device Name

Device Name:	4 Fr Single Lumen Groshong®NXT PICC Catheter
Trade Name:	4 Fr Single Lumen Groshong®NXT PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS - Long Term Intravascular Catheter
Classification Panel:	General Hospital

6.3 Predicate Device(s):

Device Name:	5 Fr Dual Lumen Groshong® NXT PICC Catheter
Trade Name:	Groshong®NXT PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital
Premarket Notification:	K023374

6.4 Device Description

The 4 Fr single lumen silicone Groshong® NXT PICC catheter is a 60 cm, trimmable catheter with depth markings. It has a closed, rounded, atraumatic, radiopaque distal tip with the 3-position, pressure-sensitive Groshong® valve.

It has a 2-piece connection with extension leg and luer lock connector that is designed to be attached by the clinician after trimming the catheter tube to length. The connector has suture wings that are StatLock-compatible for stability.

6.5 Intended Use

The 4 Fr Single Lumen Groshong® NXT PICC Catheter is designed for use in short term or long term intravenous therapy and any other therapies requiring long term central venous access (e.g. blood sampling). It is used for administration of hyperalimentation, chemotherapy and other I.V. fluids. The dual lumen feature permits simultaneous infusion of incompatible solutions and/or aspiration of blood samples. Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information.

This is the same intended use as previously cleared for the 5 Fr DL Groshong® NXT PICC Catheter, K023374.

6.5 Technological Characteristics Summary

New device is compared to Marketed Device

Yes.

Does the new device have the same indication statement?

Yes. However, there are minor modifications to the indication verbiage.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The basic fundamental scientific technology of the catheter has not changed. However, the 4 Fr SL Groshong® NXT PICC has some minor differences from the predicate 5 Fr DL Groshong® NXT PICC.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. Design performance is in compliance with the FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/ 95.*

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.

Do performance data demonstrate equivalence?

Yes. Performance data gathered in design verification testing demonstrated that the Groshong® NXT PICC is substantially equivalent to the predicate 5 Fr DL Groshong® PICC.

6.6 Nonclinical Performance Testing

Testing was performed using the *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95* included assessments of:

1) Dimensions
2) Priming Volume
3) Flow Rate
4) Tensile, Elongation and Stiffness (Modulus) of Catheter Shaft
5) Tensile - Extension Leg to Proximal (2-piece) Connector
6) Tensile - Proximal connector to Distal Connector (2-piece)
7) Tensile - Catheter Shaft to Distal (2-piece) Connector
8) Catheter Tip Tensile
9) Assembly Leak (Leak at Hub)
10) Catheter Assembly Burst
11) Catheter Collapse
12) Catheter Flexural Fatigue Tolerance (Cyclic Flexure)

Additional non-guidance testing performed:

13) Creep (Static)
14) Radiopacity
15) Valve Function
16) Kink Resistance
17) Stylet Drag
18) Flush-through Wire/luer lock connector tensile
19) Flush-through Sytlet Luer Taper
20) Flush-through Stylet Air Leakage
21) Flush-through Stylet Ease of Assembly

6.8 Conclusion

The 4 Fr SL Groshong® NXT PICC is substantially to the predicate device 5 Fr DL Groshong® NXT PICC, K023374, cleared December 18, 2002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2004

Ms. Peggy Keiffer
Senior Regulatory Affairs Manager
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K034020
Trade/Device Name: 4 Fr Single Lumen Groshong® NXT PICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted Long-tem Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 22, 2003
Received: December 24, 2003

Dear Ms. Keiffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

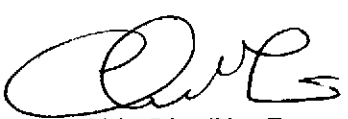
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.2

4 Fr Single Lumen Groshong® NXT PICC Catheter 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Manager of Bard Access Systems, that this notification [510(k)] for the following devices, 4 Fr Single Lumen Groshong® NXT PICC Catheter, is indicated for the following:

The Groshong® NXT PICC provides short (less than 30 days) or long (greater than 30 days) term peripheral access to the central venous system for intravenous therapy or blood sampling.

Typed Name: Peggy Keiffer
Senior Regulatory Affairs Manager

Date: 12.27.03

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number K034020

Prescription Use ✓ OR Over-The-Counter Use ____

Viola Hubbard, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K034020

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